MAY 18 2007

510 (k) Summary

Prepared:	March 8, 2007 K070688
Applicant:	Nexa Orthopedics, Inc. 11035 Roselle Street San Diego, CA 92121
Contact:	Louise M. Focht
Device Name:	Nexa Staple
Device Trade Name:	NexFix™ Compression Staple
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
Product Code:	87 JDR
Registration Number:	2030833
Owner Operator Number:	9028319

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Legally marketed device to which substantial equivalence is claimed:
The legally marketed devices to which substantial equivalence is claimed are the K043059 Wright Medical Compression Staple and simple staple, K011716 New Deal UniClip Staple, and K060014 Intelifuse Warmsystem with StimuLinks

Device Description:
The Nexa Orthopedics NexFix™ Compression Staple is made of Stainless Steel intended to be implanted into the bones of the fore foot, mid foot and hind foot. The staples are provided in 21 sizes. The staples are used for fracture fixation, fusion, and osteotomy of the bones of the hand and foot.

Intended Use:
The Nexa Staple is indicated for fixation of fracture, fusion, and osteotomies of the hand, fore foot, mid foot and hind foot.

Summary of Technologies:
The device and the predicate devices have similar design characteristics and intended use. Information provided in the application demonstrates the Nexa device is substantially equivalent to the predicate device.

Non-Clinical Testing: Non-Clinical laboratory testing was performed to determine substantial equivalence. The results indicate that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nexa Orthopedics, Inc
% Ms. Louise M. Focht
11035 Roselle St.
San Diego, California 92121

MAY 18 2007

Re: K070688
Trade/Device Name: NexFix™ Compression Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: March 8, 2007
Received: March 13, 2007

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (If Known): K070688
Device Name: NexFix™ Compression Staple

Indications for Use:

The NexFix™ Compression Staple is indicated for fixation of fracture, fusion, and osteotomies of the hand, fore foot, mid foot and hind foot.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070688